IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Paul R. LESCH, JR.	Confirmation No.: 6851
Application No.: 09/692,123	Group Art Unit: 3763
Filing Date: October 20, 2000	Examiner: Christopher Koharski
For: MEDICAMENT CARTRIDGE AND INJECTION DEVICE	Atty. Docket No.: 88066-5700

SUPPLEMENTAL RESPONSE

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Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

Sir:

Further to the Request for Continued Examination and Amendment filed on September 12, 2007, submitted herewith is Declaration under 37 C.F.R. § 1.132 of Paul R. Lesch, Jr. ("Lesch Declaration"). Entry of the Lesch Declaration and the following comments into the file of this application is respectfully requested.

Rejection Under 35 U.S.C. § 102(b)

In the office action mailed March 12, 2007, claims 1-6, 9-10, 12-13, 16-20, 22-27, and 30 were rejected under 35 U.S.C. § 102(b) as anticipated by U.S. Patent No. 4,968,302 to Schluter et al. Claims 1-6, 9-10, 12-13, 16-20, 22-28, and 30-31 were rejected under 35 U.S.C. § 102(b) as anticipated by U.S. Patent No. 4,258,713 to Wardlaw.

As explained in the September 12, 2007 Amendment, both Schluter and Wardlaw are directed to a type of hypodermic injector well known as "autoinjectors" (Amendment at pp. 9-10). The Lesch Declaration further evinces that such autoinjectors are structurally and functionally different from a jet injector and deliver the medicament in a different manner from a jet injector. In particular, the Lesch Declaration states that persons of ordinary skill in the art knew at the time of filing that an autoinjector is a traditional hypodermic injector that includes a

mechanism for automating the driving of the injector and therefore employs a relatively slow injection and deposits the injected medicament in the same manner as would a hand-powered hypodermic syringe (Lesch Declaration at ¶ 4).

By contrast, independent claims 1, 17, 18, and 30 recite a jet injector, which is very different from an autoinjector. Further to the explanations in the September 12, 2007 Amendment, the Lesch Declaration shows that a person having ordinary skill in the art would have understood a "jet injector" to be a particular class of injector that have particular medicament delivery characteristics, i.e., injection by creating a high speed jet of the medicament that is powerful enough to penetrate the tissue of the patient to a significant distance beyond the exit of the injector, which require significant structural elements that are different from those of a hypodermic injector (Lesch Declaration at ¶¶ 5-6). Compared to a hypodermic injector, a jet injector requires a substantially more powerful and faster energy source and firing mechanism to generate the jet, a carefully dimensioned and configured jet nozzle to efficiently form the high speed jet, and a significantly more robust medicament container and supporting structure to contain the elevated pressures and withstand the shock produced by the rapid and powerful firing of the jet injector (*id.* at ¶ 6). Also, because of the high speed and pressure requirements, jet injectors are not powered by pressing directly on a plunger by hand, and the firing mechanism thus does not mimic a hand-powered injector (*id.*). These structural features result in very different dispersion characteristics of the medicament into the tissue of the patient and provides must faster absorption of the medicament compared to a hypodermic injector (Amendment at p. 10).

In addition, as stated in the Lesch Declaration, one of ordinary skill in the art would have understood, in view of the disclosure in the application and knowledge in the art, how to make the jet injector recited in the present claims, including the needle-assisted type of jet injector recited in claim 5 (Lesch Declaration at ¶¶ 7-8). A jet injector can be needle-free or needle-assisted as one of ordinary skill in the art would have known at the time of filing, but whether needle-free or needle-assisted, a jet injector provides significantly deeper penetrations into the tissue than the needle tip, and provides dispersion characteristics very different from an autoinjector, with the medicament typically being absorbed much faster by jet injection (*id.* at ¶ 7).

As such, the Examiner's statement in the office action that the injectors of Schluter and Wardlaw contain structurally similar elements that meet the claim limitations and are capable of dispersing the medicament in the manner of a jet injector is incorrect. Since Schluter and Wardlaw are directed to a completely different type of injectors having significantly different structural and delivery characteristics from the jet injectors recited in claims 1, 17, 18, and 30, these references cannot anticipate and do not suggest the invention of claims 1, 17, 18, and 30.

Rejection Under 35 U.S.C. § 103(a)

The Examiner rejected claims 7, 11, 15, 21, and 29 under 35 U.S.C. § 103(a) as obvious over Schluter in view of U.S. Patent No. 5,865,799 to Tanaka et al. As explained in the September 12, 2007 Amendment, however, none of the cited references renders the claims obvious, either alone or in combination, because all of the references are directed to a hypodermic injector and are not readily modifiable to be jet injectors. The Lesch Declaration further shows that one of ordinary skill in the art would have found that Schluter and Wardlaw disclose autoinjectors, that Tanaka discloses a hand-operated pre-filled syringe, and that none of these references alone or in combination provides any teaching or suggestion or motivation to modify any of the disclosed devices to provide a jet injector (Lesch Declaration at ¶ 9).

In fact, that the devices disclosed in the references cannot readily be modified to be jet injectors because of the significant structural requirements of a jet injector (Lesch Declaration at ¶ 10). Compared to a hypodermic injector, a device configured for jet injection, as defined in claims 1, 17, 18, and 30, requires a significantly more robust medicament chamber and supporting structure to contain and withstand the elevated pressures and the shock produced by the rapid and powerful firing, such that it would not be a mere matter of strengthening the devices or providing bigger energy sources of these references to convert them to jet-inject the medicament (*id.*). In addition, producing a jet requires a careful combination of an energy source with the jet orifice, such as involving careful selection of a needle configuration, which would require more than routine optimization and design choice.

As the Lesch Declaration explains, the devices disclosed in Schluter and Wardlaw are not readily modifiable to have a sufficiently robust structure to be jet injectors. For example, Schluter requires a needle that one of ordinary skill in the art would understand is highly unlikely

to be able to withstand the high pressures and shock of a sudden, high powered firing if it were used in jet injection (Lesch Declaration at ¶ 11). Other features of Schluter, such as the very thin lifting-sealing element (29), which one of ordinary skill in the art would find unlikely to resist high pressures of jet injection and more likely to release the seal under the pressure, also make it apparent that its structure is unsuitable for jet injection (*id.*). Similarly, in Wardlaw, the disclosure of the ferrule and foam column arrangement for holding the needle does not provide to one of ordinary skill in the art a teaching or suggestion of a structure sufficiently robust to be capable of withstanding the rigors of jet injection, and the structure likely would not maintain the proper positioning of the needle during a high-powered injection such as that used in the presently recited jet injection (*id.*).

Thus, none of the cited references, alone or in combination, render the present claims obvious, and it would not have been obvious to one of ordinary skill in the art to provide the jet injector of claims 7, 11, 15, 21, and 29 in view of Schluter and Tanaka.

Accordingly, all rejections under 35 U.S.C. §§ 102(b) and 103(a) should be withdrawn.

In view of the foregoing, the entire application is now believed to be in condition for allowance, early notice of which would be appreciated. Should the Examiner not agree, then a personal or telephonic interview is respectfully requested to discuss any remaining issues in an effort to expedite the allowance of this application.

No fee is believed to be due for this submission. Please charge any required fees to Winston & Strawn LLP Deposit Account No. 50-1814.

Respectfully submitted,

Date: October 18, 2007

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